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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,935	12/22/1998	JACQUES DUMAS	BAYER 12P1	7400

7590 01/11/2005

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
ARLINGTON COURTHOUSE PLAZA I
2200 CLARENDON BOULEVARD
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

MITCHELL, GREGORY W

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,935

Applicant(s)

DUMAS, JACQUES

Examiner

Gregory W Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

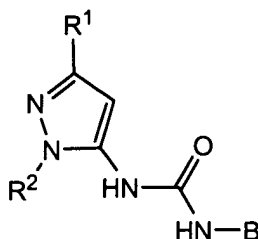
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the remarks and affidavit filed May 18, 2004 and the Request for Continued Examination filed October 18, 2004. Claims 1-30 are pending and are examined herein. Applicant has elected rheumatoid arthritis as the species of disease to be treated by the instant invention. A specific search of Applicant's elected species of compound was not found. Accordingly, Examiner has expanded the search to include the compounds of the following formula:



Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 18, 2004 has been entered.

Response to Remarks/Affidavit

The declaration filed on May 18, 2004 under 37 CFR 1.131 is sufficient to overcome the Regan et al. (USPN 6080763) reference. Accordingly, the 35 U.S.C. 103

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rejection of the previous Office Action is hereby withdrawn. The following new grounds of rejection now apply.

Claim Objections

Claim 1 is objected to because of the following informalities: the =O bond is above the NH-C bond, not above the C atom in formula I. Appropriate correction is required.

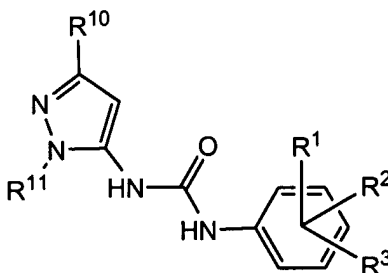
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Creswell et al. (USPN 5162360) in view of Adams et al. (USPN 5658903).

Creswell et al. teaches the treatment of hypercholesterolemia and atherosclerosis with 250 to 3000 mg/day (or 5 to 40 mg/kg) of substituted diazoles of the structure:



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wherein R1, R2 and R3 are selected from hydrogen, fluorine, chlorine, bromine, alkyl, substituted or unsubstituted benzoyl, etc.; R10 is selected from alkyl having 1-16 carbon atoms, etc.; and R11 is selected from benzyl, 2-pyridyl, and hydrogen (See Abstract; col. 3, lines 25-50; col. 5, lines 55-66). Creswell et al. does not specifically teach the treatment of rheumatoid arthritis or the p38 activity of the compounds taught therein.

Adams et al. teaches a substituted diazole for the treatment of p38 kinase mediated diseases. Adams et al. teaches that p38 kinase mediated diseases are selected from sepsis, atherosclerosis, rheumatoid arthritis, etc. See col. 38, lines 4-24; col. 65, lines 29-31.

It would have been obvious to one of ordinary skill in the art to treat rheumatoid arthritis with a diazole within the scope of the instant claims because (1) such diazoles are within the scope of compounds taught by Creswell et al. for the treatment of atherosclerosis; (2) Adams et al. teaches that atherosclerosis is a p38 mediated disease treatable by a similar diazole; (3) Adams et al. teaches that the treatment of both atherosclerosis and rheumatoid arthritis possess a similar etiology in that both are p38 mediated diseases; and (4) Adams et al. teaches that both atherosclerosis and rheumatoid arthritis are treatable in an identical manner, namely that both are treated by the diazoles taught therein. One would have been motivated to treat rheumatoid arthritis with a diazole of the instant invention because of an expectation of success in treating a disease (rheumatoid arthritis) known to be mediated in a similar manner to a disease (atherosclerosis) known to be treatable with the same diazole.

It is also noted that since both atherosclerosis and rheumatoid arthritis are both p38 mediated diseases, as taught by Adams et al., the treatment of a patient for atherosclerosis would, itself, also treat a patient for rheumatoid arthritis. Administration of the same compound/composition to the same patient in the same dosage will have the same effect, whether or not that effect was disclosed in the prior art.

It is noted that the dosage taught by Creswell et al. is within the dosage range taught by Applicant to be an effective amount: 0.01 to 200 mg/kg (page 20 of the specification). It is also noted that the limitation of claim 24, wherein Applicant limits the claim by reciting a value of p38 activity, is a *property* of the compounds claimed. Since the compound rendered obvious by the prior art is the same as the compound taught, the properties must be the same. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Conclusion

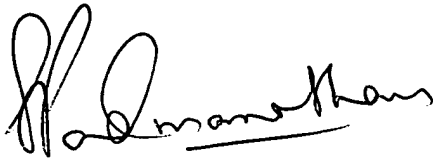
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER